Virginia Department of Health –Division of Disease Prevention: nPEP Guidelines for Local Health Departments

In 2016, the Centers for Disease Control and Prevention (CDC) released its updated guidelines for the use of nPEP for the prevention of HIV infection. The following CDC documents are available:

- *Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV- United States, 2016* (http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf)
- *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update* (https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf)
- *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2017 Clinical Providers' Supplement* (https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf)

I. Summary: Purpose of nPEP

Non-Occupational Post-Exposure Prophylaxis (nPEP) is an emergency antiretroviral treatment used to reduce the likelihood of acquiring an HIV infection after a potential exposure from a person of unknown HIV status or a person who is HIV positive, through non-occupational means, including:

- Receptive or insertive anal sex
- Receptive or insertive vaginal sex
- Sharing injection drug equipment

nPEP must be taken within 72 hours of potential exposure event(s) and is not intended for ongoing use.

Historically, nPEP has been primarily prescribed for victims of sexual assault. **However, recently updated guidelines from the Centers for Disease Control indicate that nPEP may also be prescribed after any encounter that may result in HIV transmission. Encounters include, but are not limited to, condomless sex, needle sharing, or sharing other drug paraphernalia.**

As a secondary prevention measure, nPEP is not intended to be an individual's only prevention method. Consistent condom use, using clean unshared needles, and other prevention measures should be practiced correctly and consistently while the patient is on nPEP and after the course of medication. Providers should discuss these primary prevention methods for the prevention of HIV, Hepatitis A, B, and C, gonorrhea, chlamydia, syphilis, and other sexually transmitted or bloodborne diseases. Inability to practice these behaviors correctly or consistently does not exclude a person from being prescribed nPEP, but does offer an opportunity to further discuss risk reduction and primary prevention. PreExposure Prophylaxis (PrEP) is a long-term option for preventing transmission of HIV for individuals who engage in high-risk behaviors.

General Information:

nPEP is a 28-day regimen, typically consisting of Tenofovir 300 mg PO daily + Emtricitabine 200 mg PO **once** daily **plus** Raltegravir 400 mg PO **twice** daily or Dolutegravir tab 50 mg PO **once** daily (see note below). This dosage is should be adjusted for weight when prescribed to patients under 18 years old. Patients with compromised kidney function may require dosage adjustments. Please refer to page 9 of this document; CDC Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016; and/or manufacturers' dosing information for specific guidance.

A preliminary unscheduled analysis of data from an ongoing NIH-funded observational study in Botswana suggests that an increased risk of neural tube defects was associated with exposure to antiretroviral (ARV) regimens that include **dolutegravir** (DTG) at conception. Therefore, health care providers prescribing nPEP should avoid use of **dolutegravir** (DTG) for:

--Nonpregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method; and,
--Pregnant women early in pregnancy since the risk of an unborn infant developing a neural tube defect is during the first 28 days.

Prior to beginning nPEP, medical staff will need to know the patient's medical history and all medications the patient is currently taking to determine if there are potential drug interactions that may occur or interfere with the nPEP course of treatment. **Patients may initiate nPEP treatment without yet having lab results or knowing the HIV status of themselves or source person of exposure, as nPEP must be initiated as soon as possible within 72 hours of**

exposure. Testing using fourth-generation EIA or HIV RNA assay should be conducted as soon as possible, before or after initiation of treatment. Patients must also undergo several other lab tests, including tests to measure kidney and liver function, Hepatitis B and C tests, chlamydia, gonorrhea, syphilis tests, and a pregnancy test (if applicable). If the HIV test result for the individual receiving treatment is HIV positive, the patient should cease nPEP treatment immediately and be referred to a provider for HIV management.

If feasible, testing for the source person may be performed. If the source person's HIV test result is negative, the provider should consult with the nPEP patient to determine if continued treatment is appropriate. Situations that may warrant continuation of nPEP include the possibility that the source person may be infected but not yet seroconverted or that the nPEP patient has a history of other potential exposures within the 72-hour window prior to treatment. It is essential to comply with patient confidentiality standards at all times.

II. Eligibility:

PATIENT MUST:

- be 18 years or older
    - if younger than 18, must have consent from parent or legal guardian OR be an emancipated minor.
- be a Virginia resident, if state funding is necessary for prescription and/or lab work funding assistance.
- **in the last 72 hours,** have been exposed to blood, genital secretions, or other potentially infected body fluids of a person known to be HIV infected or of unknown HIV status when that exposure represents a substantial risk for HIV acquisition.

AND

- Clinical determination by the prescribing medical provider based on best-evidence for use of nPEP as an HIV secondary prevention tool for an HIV negative person.

- **FINANCIAL ELIGIBILITY:** DDP provides nPEP to both insured and uninsured residents of Virginia at no cost. Uninsured individuals may receive the full 28-day course of medication, provided they meet programmatic guidelines outlined below. Insured individuals may receive up to a five-day supply of medication. This is intended to expedite access to the medication while the individual navigates insurance or patient assistance programs. Access to medication is provided through local health departments (LHDs). Please see Appendix A for more information on assistance for insured individuals.

III. Patient Education and Resource Navigation:

It is important to provide patients with comprehensive education as to the function, effectiveness, and risks of nPEP before treatment, and provide ongoing patient support during the 28-day course. Clinical staff should provide information on both physical and mental health service options that are available to help ensure adherence and reduced risk. Appendix A provides a comprehensive list of discussion points and psychosocial factors to discuss with patients.

Patient Education and Informed Decision Making

Patient education is critical to shared decision-making and the success of nPEP as part of the secondary prevention plan. Patient education also sets the stage for further primary prevention. Medication adherence may be improved when patients participate in treatment decisions.

Patient should be informed of:

1. How nPEP works
2. Limitations of nPEP
3. Potential side effects associated ARV treatment
4. Long-term safety of nPEP
5. Symptoms of seroconversion
6. Importance of daily adherence for the full 28 days
7. Note for those who may be pregnant: There have been no studies that have looked directly at the impact of nPEP on a developing fetus; however, nPEP has been shown to provide protection against HIV infection to both the mother and the fetus

Providers should work to ensure that patients understand how nPEP works, including the risks and benefits, and the need for strict adherence. Explanations should be given in the patient's native language and should be easy to understand. See Appendix B.

Providers should obtain a sexual and drug-use history, and discuss risk-taking behaviors with patients. In cases of sexual assault, use additional care when discussing risk factors and provide information on support services for sexual assault survivors. Providers should present patients with behavior-appropriate safer sex practices and safer injection techniques as well as assist patients in planning future primary prevention. This discussion should include PrEP if the patient's exposure factors are persistent and include any of the following high-risk behaviors:

- Men who have sex with men who engage in unprotected anal intercourse
- HIV-negative individuals who are in a sexual relationship with a known HIV-infected partner

- Male-to-female and female-to-male transgender persons engaging in high-risk sexual behaviors or sharing needles for non-prescribed drugs such as hormones or silicone
- Individuals engaging in transactional sex, such as sex for money, drugs or housing, or those working in the commercial sex industry
- Drug users who report any of the following behaviors: sharing injection equipment and/or works and/or engaging in high-risk sexual behavior
- Individuals diagnosed with at least bacterial sexually transmitted infection in the last six months, who still practice high risk behaviors
- Individuals who have been prescribed nPEP more than once
- Patients may begin taking PrEP immediately at the conclusion of a 28-day course of nPEP treatment, pending negative HIV test results. Refer to CDC PreExposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update for guidelines on transitioning from nPEP treatment to PrEP therapy.

IV. Clinical Screening

Diagnostic Testing Recommended by the CDC (continued on next page):

Test	Source	Exposed persons			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
		For all persons considered for or prescribed nPEP for any exposure			
HIV Ag/Ab testing[a] (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓[b]
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓[c]
Hepatitis C antibody test	✓	✓	—	—	✓[d]
		For all persons considered for or prescribed nPEP for sexual exposure			
Syphilis serology[e]	✓	✓	✓	—	✓
Gonorrhea[f]	✓	✓	✓[g]	—	—
Chlamydia[f]	✓	✓	✓[g]	—	—
Pregnancy[h]	—	✓	✓	—	—
		For persons prescribed tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir			
Serum creatinine (for calculating estimated creatinine clearance[i])		✓	✓	—	—
Alanine transaminase, aspartate aminotranferase		✓	✓	—	—
	For all persons with HIV infection confirmed at any visit				
HIV viral load	✓	✓[j]			
HIV genotypic resistance	✓	✓[j]			

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

[a] Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

[b] Only if hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.

[c] If exposed person susceptible to hepatitis B at baseline.

[d] If exposed person susceptible to hepatitis C at baseline.

[e] If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment

[f] Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification tests (NAAT). For patients diagnosed with a chlamydia or gonorrhea infection, retesting 3 months after treatment is recommended.

- For men reporting insertive vaginal, anal, or oral sex, a urine specimen should be tested for chlamydia and gonorrhea.
- For women reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive oral sex, an oropharyngeal swab should be tested for gonorrhea. (http://www.cdc.gov/std/tg2015/tg-2015-print.pdf)

[g] If not provided presumptive treatment at baseline, or if symptomatic at follow-up visit.

[h] If woman of reproductive age, not using effective contraception, and with vaginal exposure to semen; see warning re. use of dolutegravir in women of reproductive potential.

[i] eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 − age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females).

[j] At first visit where determined to have HIV infection.

Other important considerations when prescribing nPEP:

- **Is the patient pregnant or attempting to conceive?**

  Health care providers prescribing PEP should avoid use of DTG for:

  - Non-pregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method; and,

  - Pregnant women early in pregnancy since the risk of an unborn infant developing a neural tube defect is during the first 28 days. Ask all patients who are able to conceive about pregnancy status, and advise pregnant patients on additional risks and benefits of nPEP during pregnancy.

- **Does the patient have a history of liver or kidney disease which may be exacerbated by nPEP medications?**

  A review of patient's medical history and current medications should be completed before initiating nPEP. Patient use of medications that reduce kidney renal function or compete for active renal tubular secretion should be considered before prescribing nPEP. Monitor these patients for dose-related renal toxicities. Patients with a history of liver disease and should be monitored for signs of hepatotoxicity.

- **Is the patient taking concomitant nephrotoxic drugs or drugs that may interact with nPEP medications?**

  Obtain a thorough medication history and consult the medication package insert for additional information on drug interactions.

- **Does the patient have osteopenia/osteomalacia/osteoporosis?**

  There may be a risk of bone loss associated with tenofovir. Though the duration of nPEP is brief, the dosage is high. Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis /osteomalacia/ osteopenia.

- **Is the patient an adolescent?**

  nPEP is approved for use by individuals younger than 18 years old younger with the consent of their legal guardian or if the individual is an emancipated minor.

  Medication and dosage for those younger than 18 may be different that adult dosage based on age and weight of patient (see following charts for tenofovir DF+emtricitabine, raltegravir and dolutegravir information)

  VDH Central Pharmacy is able to fill pediatric doses, though slower delivery is expected and greater coordination is needed with the pharmacy.

V. Medication Dosing

Tenofovir DF+emtricitabine dose is weight-based. It is <u>not</u> indicated in pediatric patients weighing less than 17 kg.

Weighing 35 kg or more	tenofovir DF+emtricitabine 200/300 mg once daily	Stocked in pharmacy
Weight 28 to less than 35 kg	tenofovir DF+emtricitabine 167/250 mg once daily	*Dosage available, but not stocked in pharmacy*
Weight 22 to less than 28 kg	tenofovir DF+emtricitabine 133/200 mg once daily	*Dosage available, but not stocked in pharmacy*
Weight 17 to less than 22 kg	tenofovir DF+emtricitabine 100/150 mg once daily	*Dosage available, but not stocked in pharmacy*
Weighing less than 17 kg	Use has not been evaluated; do not administer	

Raltegravir may be prescribed to patients 4 weeks and older weighing at least 3 kg; dose is weight-based. It is not indicated in pediatric patients younger than 4 weeks.

Weight 25 kg or more	raltegravir 400 mg twice a day	Stocked in pharmacy *(chewable available and may be preferred for this population but this formulation is not stocked in pharmacy)*
Weight 20 - <25 kg	raltegravir 150 mg twice a day	*Dosage available with chewable tablets but not stocked in pharmacy*
Weight 14 - <20 kg	raltegravir 100 mg twice a day	*Dosage available with chewable tablets but not stocked in pharmacy (oral suspension form not available)*
Weight 11 - <14 kg	raltegravir 75 mg twice a day	*Dosage available with chewable tablets but not stocked in pharmacy (oral suspension form not available)*
Weight 8 - <11 kg	raltegravir 60 mg twice a day	*Oral suspension not available*
Weight 6 - <8 kg	raltegravir 40 mg twice a day	*Oral suspension not available*
Weight 4 - <6 kg	raltegravir 30 mg twice a day	*Oral suspension not available*
Weight 3 - <4 kg	raltegravir 20 mg twice a day	*Oral suspension not available*

Dolutegravir may be prescribed to patients 12 years and older weighing at least 30 kg. It is not indicated in pediatric patients younger than 12 years of age or less than 30 kg. Please see CDC's Interim Statement regarding the use of DTG in women of reproductive potential.

30 to less than 40 kg	35 mg once daily	
40 kg or greater	50 mg once daily	*Stocked in pharmacy*

VI. nPEP Timeline and Management

Prescription of nPEP should be provided as soon as possible, and fill requests should be made immediately to ensure that patients are able to begin treatment as soon as possible. **Patients must begin nPEP within 72 hours of exposure to be effective.**

At initial visit:

•Discuss nPEP use; clarify misconceptions, emphasize that patient must maintain use for full 28 days, twice a day, at the same time each day

• Perform lab tests according to CDC guidelines on pages 6 and 7.

Neither test results nor the tests themselves are required to initiate nPEP, provided an assessment of risk and screening of possible complications or considerations (i.e. pregnancy or HCV) are conducted with patient.

Prescribe 28-day supply of nPEP

•Follow up weekly to assess side effects, and adherence, either in person or by phone.

•Discuss test results with patient, and advise both on results' potential impact on treatment, and follow-up care needed for any diagnoses made

•If HIV test results are positive, discontinue nPEP.

4 to 6 week-up follow-up

•Provide all recommended tests and follow-up accordingly.

•Conduct further risk assessment with patient.

If exposure risk recurrent, discuss risk reduction plan including PrEP.

Though nPEP and PrEP cannot be taken at the same time, a patient may initiate PrEP treatment immediately after 28 day course of nPEP.

3-month visit and 6-month visits

- Provide additional testing according to CDC guidelines on pages 6 and 7.
- Continue to work with patients to discuss any ongoing exposure risks and risk reductions strategies such as use on PrEP

VII. Adherence Counseling

nPEP only is effective as a post-exposure tool to prevent acute HIV infection if the patient takes the medication as prescribed for 28 days.

Though nPEP is not a long-term commitment, helping the patient form strategies that ensure adherence may be useful. Strategies may include formulation of a patient-centered adherence plan, which accounts for times of day to take the drug, storage, what to do if the patient misses a dose, and what to do if side effects occur. Adherence is often compromised by other factors such as mental illness, substance use, lack of stable housing, and interpersonal violence. Clinical staff and the patient should discuss barriers to adherence and possible means of overcoming these barriers prior to the patient being prescribed nPEP. More information on talking to the patient about these topics can be found in Appendix B.

Linkage to services offered by community-based organizations (CBOs) or other service organizations may provide interventions that may help increase patient adherence. If the clinical staff feels these linkages may be useful to the patient, a referral can be made to CBOs (see resource list). DDP's HIV/STD/Hepatitis Hotline is also available to provide adherence counseling and resources for patients on nPEP.

VIII. Prescription and Pharmacy Procedures

Due to the time sensitivity of nPEP, it is important to move quickly to have the prescription filled and received by the patient within 72 hours of the exposure. Please contact Virginia Department of Health (VDH) staff **(please see the table below for contact information)** as soon as possible to ensure that all required information is collected from patient, clarify timeline, and be sure that the patient will be able to receive the medication within the window period. In the event that it is not possible to have the medication shipped and received within the 72-hour window, VDH will discuss other options with clinical staff or patient.

For the purposes of this program, nPEP prescriptions must originate at a participating LHD and medications **must** be shipped to either the patient's home, the ordering LHD or another health department site. Because of the urgent nature of the nPEP, all related processes can and should be done via telephone. Please call 804-864-7938 to complete the application process.

The following patient information is required:

- Full legal name
- **Date and time of exposure**
- Sex at birth
- Gender identity
- Date of birth
- Phone number and if we are able to leave voice mail
- Home address
- Mailing address, if different than home address
- Race
- Hispanic or Latino ethnicity
- Name and address of LHD for medication to be sent
- Contact information for the prescriber
- Type of exposure, if available

Once a telephone application is approved, VDH staff will notify the prescriber who should then phone a verbal order to Central Pharmacy at 804-371-0236. VDH staff will follow up with Central Pharmacy to coordinate delivery within the necessary time frame. If the prescription and application are received by 1 p.m. on a business day, it may be possible to have the medication shipped to the prescriber or the patient the same business day and received the next business day. Otherwise, it may be shipped out the next morning and received on the following business day.

If the program support specialist is not available, please contact the PrEP Coordinator, Eric Mayes at 804-864-7335. If neither is available, call the Disease Prevention Hotline 800-533-4148 for further assistance.

Important Numbers

Program Support Specialist, Maurice May	804-864-7938
PrEP Program Coordinator, Eric Mayes	804-864-7335
Nurse Practitioner Consultant, Linda Whiteley	804-864-7328
VDH Disease Prevention Hotline	800-533-4148
Central Pharmacy Phone	804-786-4326
Central Pharmacy Fax	804-371-0236
VDH Prevention Fax	804-864-8053

Review of Steps

- Upon patient receiving prescription, call VDH to discuss patient options.
    - Please do not hesitate to reach out to VDH staff with questions, concerns, or special patient considerations.
- Verbally review application with VDH staff.
- Upon approval of application phone verbal order to Central Pharmacy at 804-786-4326.
- VDH staff will advise when to anticipate the medication delivery.
- If medication is delivered to a LHD, have the client sign the medication order form and fax to VDH.

IX: Evaluation and Client Consent

DDP will regularly conduct evaluation in order to determine program effectiveness and to assist in similar future projects. Patients receiving DDP-funded medications must consent to participate in the evaluation process. Other participants should be encouraged to participate in evaluation as well. This process involves:

1. Permission for LHD to share information on behavioral risks, HIV/STD/hepatitis status, and drug adherence with VDH-DDP program staff.
2. Completion of short follow-up and patient satisfaction survey (paper or online) at end of patient participation.

X. Resources

DDP HIV STD HEPATITIS Hotline: 800-533-4148

VDH-DDP Contact Information:

Program Support Specialist, Maurice May	804-864-7938
PrEP Program Coordinator, Eric Mayes	804-864-7335
Nurse Practitioner Consultant, Linda Whiteley	804-864-7328
VDH Disease Prevention Hotline	800-533-4148
Central Pharmacy Phone	804-786-4326
Central Pharmacy Fax	804-371-0236
VDH Prevention Fax	804-864-8053
Social Media Coordinator, Chris Barnett	804-864-8110

APPENDIX A

Resources for Insured Patients

Both Virginia Medicaid and Medicare formularies list nPEP medications and are available to patients without HIV infection at the discretion of a prescribing provider.

Co-pay costs will vary among insurance plans. There are several co-pay assistance programs available from the makers of each medication:

- **tenofovir DF+emtricitabine (Truvada^{R}) - Gilead:** 1-877-505-6986 or http://www.gileadcopay.com/
- **raltegravir (Isentress^{R}) - Merck:** 1-855-834-3467 or https://www.activatethecard.com/7119/#
- **dolutegravir (Tivicay^{R}) - ViiV:** 1-877-784-4842 or www.viivhealthcareforyou.com

Additionally, the Patient Access Network Foundation (PAN) is a non-profit organization that provides assistance to under-insured patients for out-of-pocket expenses for HIV treatment and prevention, including PrEP or nPEP. **Patient insurance must cover the medications prescribed as a part of nPEP.** Apply online by at https://www.panapply.org/ or by calling 1-866-316-7263.

APPENDIX B

Educational and Psychosocial Tools

Pre-Prescription: Education and Counseling

Patients need to understand how nPEP works, including risks and benefits, the need for strict adherence to help the body prevent infection, and what nPEP will and will not do for them. Explanations should be given in the patient's preferred language and be easy to understand.

For example:

> *The medications prescribed for nPEP are drugs that are commonly used to treat HIV in persons who are HIV-positive. Following an exposure to HIV, when taken daily by people who are HIV-negative, they help the body resist an HIV infection. The pill needs to be taken once [or twice] every day in order for the body to attain adequate drug levels to block HIV. It cannot be expected to work effectively if taken inconsistently or not taken the full 28 days. nPEP reduces, but does not eliminate, HIV transmission risk. You should use condoms and clean drug works while on nPEP. nPEP does not protect against other sexually transmitted or bloodborne diseases, such as gonorrhea, chlamydia, syphilis, or hepatitis A, B or C. If you feel you might need to take nPEP again, you might want to consider beginning PrEP, which is only one pill a day, and is more suitable for long term use.*
>
> n*PEP is a combination of pills that, if taken once [or twice] a day by people who are HIV negative may prevent HIV infection after a person has been exposed to the virus. It has to be taken consistently – one [or twice] daily, at the same time each day. nPEP is most effective at preventing infection if taken consistently at the same times each day for the entire 28 days. nPEP reduces, but does not eliminate, the risk of getting HIV. While you are taking nPEP, you still need to use condoms to protect against other sexually transmitted diseases such as, gonorrhea, chlamydia, syphilis, and Hepatitis A, B, and C, which are not prevented by nPEP. You also need to avoid sharing drug injection works to protect against other bloodborne diseases such as hepatitis B and C.*

Checklist 1: Patient Education and Assessment

1. **How nPEP works:**

    a. Explain how nPEP works in language that is easy to understand.

    (For example: *nPEP is a combination of several medications, that, when taken once [or twice] a day as prescribed, may prevent HIV infection after a potential exposure.*)

    b. nPEP works is a secondary prevention tool, and should not serve as a patient's only prevention strategy; it is a part of a larger comprehensive plan. If risk of exposure is ongoing, encourage the patient to consider PrEP, condoms, and other primary prevention tools.

    (For example: *nPEP does not prevent other STI's and it is recommended that you still use condoms and/or clean injection equipment while on nPEP, as well as develop or assess current prevention plan to see if it fits current risks and needs*.)

2. **Limitations of nPEP:**

    a. Efficacy is dependent on adherence.

    (For example*: nPEP ONLY helps prevent infection when taken consistently – once [or twice] daily as prescribed, at the same time each day*.)

    b. nPEP reduces the likelihood of infection after an exposure, but does not eliminate risk of HIV infection.

    (For example: *nPEP is still being studied; though a number of studies have shown that it prevents infection, several long-term risks remain unknown. When initiated within 72 hours of exposure, and taken correctly and consistently over 28 days, nPEP has been shown highly effective in preventing HIV infection.*)

    c. nPEP does not provide protection against other sexually transmitted infections such as syphilis, gonorrhea, chlamydia, or hepatitis A, B, or C.

3. nPEP use:

a. Dosing and need for daily adherence

(For example: *nPEP is a once- or twice-a-day regimen, which must be taken consistently over a 28-day period to be effective. Taking nPEP incorrectly could lead to viral resistance and other complications, so it is important that you take the pills as prescribed*.)

b. When doses are missed

(For example: *If doses are accidentally missed, do not double up doses, but take the missed mediation as soon as you can, and maintain your pill schedule after that*.)

c. Common side effects: About half of patients taking nPEP experience mild side effects in first two weeks of treatment. Side effects may include headache, nausea, fatigue, insomnia, skin sensitivity and rash. Side effects usually resolve or improve within the first two weeks.

(For example: *nPEP may cause side effects, but they are usually tolerable and diminish or disappear after a few weeks. Common side effects are headache, nausea, fatigue*.)

d. Baseline tests and schedule for monitoring

(For example: *Upon being prescribed nPEP, your health care provider will also want perform a series of medical tests including an HIV test and liver and renal function tests. nPEP medications can affect liver and kidney function, and we want to be aware of any interactions nPEP may have with other medications or conditions you may have. If you test positive for HIV, you will need to discontinue use of nPEP and go on an ART regimen appropriate for management of infection*.)

e. Elements of and schedule for follow-up monitoring, including HIV testing at 4-6 weeks, 3 months, and 6 months after exposure.

(For example: *nPEP is a 28-day prescription. After completing the 28-day regimen, you will need to come in at specified intervals so we can run tests again, including for HIV, to see if everything is going ok*.)

f. Development of acute HIV infection

(For example: *If you develop HIV infection while on nPEP, you may experience acute flu-like symptoms such as fever, sore throat, skin rash, muscle and joint aches, and headache. If this happens to you, call your health care provider immediately and arrange to have a medical evaluation that includes an HIV test as soon as possible. If you are HIV-positive, you will need to stop nPEP and may be prescribed antiretroviral therapy for the acute HIV infection.)*

4. Criteria for discontinuing nPEP

a. Positive HIV test result:

(For example: *If you test positive at any point in the 28-day treatment period, nPEP should be discontinued immediately*)

b. Development of renal disease

(For example: *nPEP may also be stopped if you develop kidney disease or your kidneys show signs of distress, but you will need to speak with your health care provider regarding the risks and benefits of treatment.)*

c. Considerations if identified source person tests negative

(For example: *If the source of the potential person source is negative, there is no need to continue taking nPEP, unless there are other mitigating factors or potential source of exposure within 72 hours of when you started taking medication.*)

5. **Potential benefits/risks if pregnant or if pregnancy occurs during use of nPEP**

(For example: *If you are pregnant or plan to become pregnant while on nPEP, please discuss the risks and benefits of nPEP with your health care provider*.)

CDC has issued an interim statement regarding Potential Fetal Harm from Exposure to Dolutegravir -- Implications for HIV Post-exposure Prophylaxis (PEP):

Health care providers prescribing [HIV postexposure prophylaxis] should avoid use of dolutegravir for--

--Non-pregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method; and,

--Pregnant women early in pregnancy since the risk of an unborn infant developing a neural tube defect is during the first 28 days.

Checklist 2: Psychosocial Wellness

Assess how psychosocial factors may influence nPEP adherence:

a. Ongoing abuse or trauma

(For example: *Has recent or current sex partner ever hit, slapped, kicked, pushed you or hurt you in any way? Could that affect your ability to take your medication once or twice a day?*)

b. Homelessness or housing insecurity

(For example: *Are you currently homeless, "couch surfing," between permanent residence somewhere? Could that make it hard to stay on your medication for the whole 28 days?*)

c. Substance use

(For example: *Do you share any injection works with other people? Do you have access to clean works or know how to wash your works? It is important for your safety and others to only used sterile syringes that are not used by other people. This is important to avoid spreading blood borne diseases like Hepatitis C and HIV.*

Do you drink more than 4-5 drinks in one sitting? How often? Has your drinking ever impacted your sexual decision making or have you done something when you were drunk you would not do when you are sober?

Have you ever taken drugs that influenced your sexual decision making, or have you done something when you are using that you would not do when you are sober?

It is important that, while you are on nPEP, you consistently practice safer sex; if you think you have may have a hard time doing this because of your drug or alcohol use, I can provide a referral for support or treatment.)

d. Mental Illness

(For example: Have you ever been told by a health care provider or mental health professional that you have a mental health disorder? Many people have some type of mental health disorder and work with mental health professionals to stay healthy through medication and other treatment. Certain mental illnesses can make it hard for you to take your medication once or twice a day. I can provide a referral if you are not currently getting the mental health support you need to maintain your overall health.)